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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 05/02/97 08/850,353 KIM PC9563JTJ **EXAMINER** HM22/0207 WHITE, E GREGG C BENSON PFIZER INC ART UNIT PAPER NUMBER PATENT DEPARTMENT EASTERN POINT ROAD 1623 GROTON CT 06340 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

02/07/00

Office Action Summary

Application No. 08/850,353

Applicant(s)

KIM

Examiner

WHITE

Group Art Unit 1623



X Responsive to communication(s) filed on Nov 29, 1999	<u> </u>
XI This action is FINAL .	
Since this application is in condition for allowance except in accordance with the practice under Ex parte Quayle, 19	335 C.D. 11; 453 O.G. 213.
A shortened statutory period for response to this action is set is longer, from the mailing date of this communication. Failur application to become abandoned. (35 U.S.C. § 133). Exten 37 CFR 1.136(a).	re to respond within the period for response will cause the
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	
Claim(s)	
Claims	are subject to restriction or election requirement.
Application Papers See the attached Notice of Draftsperson's Patent Draw The drawing(s) filed on is/are objections.	
 ☐ The proposed drawing correction, filed on ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. 	is _approved _disapproved.
Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priori All Some* None of the CERTIFIED copies received. received in Application No. (Series Code/Serial None received in this national stage application from the Certified copies not received: Acknowledgement is made of a claim for domestic priori	S of the priority documents have been Number) the International Bureau (PCT Rule 17.2(a)).
Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION O	ON THE FOLLOWING PAGES

Page 2

Serial Number: 08/850,353

Art Unit: 1623

1. The request for reconsideration under rule 111 filed November 29, 1999 has been received and entered into the record.

- 2. Claims 1-3 are pending in the case. Claims 4-15 were canceled by Applicants in there Amendment filed May 10, 1999.
- 3. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.
- 4. The Appeal is being held in abeyance.

35 USC 112, Second Paragraph Rejection

- 5. Claims 1 and 2 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons already of record on page 2 of the Office action mailed June 17, 1999
- 6. Applicant's arguments filed November 29, 1999 have been fully considered but they are not persuasive. Applicant argues against this rejection on the grounds that the term "desired target solubility" was completely clear and distinct without the abundant explanation given in Applicant's specification, but that, especially in light of the explanation (and exemplification) of "desired solubility" supplied by Applicant in the specification, one skilled in the art, would find the claims to be clear and distinct, and have no difficulty understanding the metes and bounds of the subject matter claimed. However, this argument is not persuasive since the metes and bounds of the term "desired target solubility" cannot be determined without further explanation in the claims as to the exact solubility that is desired by the Applicant. Furthermore, this terminology does not fulfill the requirement of 35 U.S.C. 112, second paragraph, since this language does not point out and distinctly claim the subject matter and the specification does not provide a standard for ascertaining the requisite degree of the term. Accordingly, the rejection of claims 1 and 2 is maintained under 35 U.S.C. 112, second paragraph.

Page 3

Serial Number: 08/850,353

Art Unit: 1623

7. Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US Patent No. 5,624,940).

- 8. Applicant's arguments filed November 29, 1999 have been fully considered but they are not persuasive. Applicants argument on pages 3 and 4 of their response filed November 29, 1999 is not persuasive since the metes and bounds of Applicants desired target solubility cannot be determined. The claims do not specific any particular salt of a compound and only indicates that the salts of the compound are being made soluble by combining the salts of the compound with cyclodextrin, which is well known in the art as indicated in the Bryant et al patent. The fact that Applicants are determining the solubility of a series of salts (which have not been specifically set forth in the claims) does not make the claims patentable over the prior art. Accordingly, the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over the Bryant et al patent is maintained.
- 9. All the pending claims of record (claims 1-3) are rejected.
- 10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Page 4

Serial Number: 08/850,353

Art Unit:

1623

Any inquiry concerning this communication or earlier communications from the examiner 11. should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

February 3, 2000

Howard C. Lee Howard C. Lee

Primary Examiner Art Unit 1623